

Remarks

The various parts of the Office Action (and other matters, if any) are discussed below under appropriate headings.

Claim Rejections - 35 USC § 102 and § 103

Claims 1-11, 13-20 and 22-23 stand rejected based on *Anderson* (U.S. 2002/0168618), *Kucharczyk* (U.S. 6,026,316) and/or *Lemelson* (U.S. 5,919,135). Withdrawal of the rejection is respectfully requested for at least the following reasons.

A. Claims 1-11 and 13-20

Independent claim 1 recites that prior to positioning an infusion or withdrawal catheter in a body of a patient, patient data is used to plan an infusion of a substance into the patient, and that the planned infusion is simulated to obtain data corresponding to a distribution of the substance within the patient.

The invention of claim 1, for example, enables a surgeon or the like, in advance to performing an infusion on a live patient, to plan the infusion of a substance into the patient and simulate the results of the infusion in a virtual setting (e.g., in a computer and displayed on a computer screen). More particularly, and as described in the specification, a “planned infusion” enables the surgeon to use different infusion parameters (e.g., different catheters, different angles and locations of entry, different depths of penetration, different infusing mediums, different pressure gradients, different volumes of substance infused into the patient, etc.), and simulate the expected results of the infusion based on the selected parameters.¹ Based on the simulated results, the surgeon can change parameters and perform additional simulations so as to determine an infusion plan that provides desired results prior to performing the actual infusion.

Anderson describes a system wherein an injection may be simulated using a simulated body cavity (e.g., a manikin). More specifically, a syringe, for example, is inserted into the manikin, and a signal receiving element receives signals from the system processor to execute contrast injection at a particular flow rate and volume.² The “simulation”, in the context of *Anderson*, refers to providing a “feel” for the physical attributes of the infusion. More specifically, the simulation of *Anderson* provides force feedback or resistance as the syringe is inserted in the manikin. Further, the simulation of *Anderson* provides visual changes on the

¹ See, e.g., page 3, lines 13-25 of the application.

² See paragraphs [0087], [0102] and [0103] of *Anderson*.

screen to make it appear as an infusion has taken place. Throughout this simulation, however, an infusion has not been planned, nor has data been obtained that corresponds to a distribution of the substance within the patient.

While *Anderson* makes reference to the fact that the device may be used for “preplanning”, this preplanning is in the context of providing the trainee surgeon (or experienced surgeon performing a new procedure) with a feel for the procedure. In other words, the system of *Anderson* provides the surgeon with the physical feedback that effectively simulates what he may feel (e.g., the level of force required to insert the syringe into the body) when performing the procedure on a live person. In this manner, the surgeon may be able to identify during a procedure on a live person when a particular step is or is not proceeding as expected. This “preplanning”, which is in the context of providing a feel for the procedure, is not planning an infusion, as recited in claim 1. The system of *Anderson* does not enable the surgeon to select different catheters, different angles, depths and locations of penetration, etc. and simulate the results of an infusion using such parameters.

Anderson does not teach or suggest *prior to positioning an infusion or withdrawal catheter in a body, an infusion of a substance into the patient is planned, said plan including performing a simulation of the planned infusion to obtain data corresponding to a distribution of the substance within the patient*, as recited in claim 1. Similar arguments apply to claims 13 and 15.

Lemelson and *Kucharczyk*, for at least the reasons discussed in the reply to the previous Office Action, have not been found to make up for the deficiencies of *Anderson*. Accordingly, withdrawal of the rejection of claims 1, 13 and 15 is respectfully requested.

Claims 2-11, 14, and 16-20 depend from one of the above claims and, thus, can be distinguished from the cited art for at least the same reasons. Accordingly, withdrawal of the rejection for claims 2-11, 14 and 16-20 is respectfully requested.

B. Claims 22-23

The Examiner contends that Applicants are reading limitations from the specification into the claims. Applicants respectfully disagree with the Examiner.

Independent claim 22 recites a device for carrying out an infusion, wherein the device includes a verification device for comparing **planned infusion data** with actual infusion data. The features of claim 22 are clear; the device compares planned infusion data with actual infusion data.

Kucharczyk does not contemplate a planned infusion and, thus, there cannot be planned infusion data. Instead, *Kucharczyk* simply describes a system that can be used to track the

distribution of a drug into a patient after the drug has been administered (e.g., images of tissue prior to the infusion are compared to images of the same tissue after the infusion). An infusion, however, is not planned and, thus *Kucharczyk* does not teach or suggest all the features of claim 22. *Lemelson* and *Anderson* have not been found to make up for the deficiencies of *Kucharczyk*.

Claim 23 depends from claim 22 and, therefore, can be distinguished from the cited art for at least the same reasons.

Accordingly, withdrawal of the rejection of claims 22 and 23 is respectfully requested.

New Claims 24 and 25

New claims 24 and 25 are submitted for favorable examination.

Conclusion

In view of the foregoing, request is made for timely issuance of a notice of allowance.

Respectfully submitted,

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